



Exemptions

Policy

- In accordance with federal regulations 45 CFR 46 and 21 CFR 50 and 56, Children's Hospital allows specific categories of research to be exempt from human subject review. Any research that falls within these categories must also present minimal risk and not subject to any state laws that would prohibit and exemption. Of these categories, category 6 (below) is the only one that is permissible if the research falls under Food and Drug Administration regulation.
- The Director of Clinical Research Compliance or the CCI Chair may determine that a human subject activity is exempt from CCI review.
- The exemptions do not apply to research that involves prisoners. See Clinical Investigation policy [Human Subject Research: Prisoners](#) for additional information about studies that involve prisoners.
- The exemption category for research that involves survey or interview procedures or observations of public behavior does not apply to children except for research involving observation of public behavior when the investigator does not participate in the activities being observed.

Purpose

The Purpose of this policy is to outline the process for determining that an activity is exempt from human subject review, and to list the specific federal regulation categories that Children's Hospital accepts as exempt.

Procedure

1. Accepted Exemption Categories

Children's Hospital will exempt from human research review only those research activities that involve human subjects that, fall within one or more of the specified exempt categories. These categories are listed below. Categories considered exempt from CCI review are as follows:

Category 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the

comparison among instructional techniques, curricula, or classroom management methods.

Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

For research that involves children as subjects, no exemptions are allowed under (b) when subjects are involved in observations in which the investigator participates in the activities being observed.

Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

Category 4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Category 5

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and are designed to study or evaluate:

- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits under those programs.

OHRP has determined that the following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs" as specified under Department of Health and Human Services (HHS) regulations at [45 CFR 46.101\(b\)\(5\)](#):

- (1) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g.,

social, supportive, or nutrition services as provided under the Older Americans Act).

- (2) The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- (3) There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
- (4) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

The funding agency must be contacted and provide approval to utilize this exemption category

Category 6

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

Exemption Review Process

1. If an investigator believes that a study meets the criteria for exemption, the principal investigator (PI) is asked to complete the Statement of Exemption Form. Investigators who are requesting an exemption for category 4 (existing specimens and data are asked to completed the discarded specimen or medical record/database review form instead. Both forms should be submitted to the Clinical Investigation Office.
2. The form asks for a brief summary of the research, and asks the investigator to indicate under which category the research is exempt.
3. The Statement of Exemption Form is reviewed by either the Director of Clinical Research Compliance or the CCI Chair. The reviewer will review the application to determine
 - Risks to subjects are minimized.
 - There are adequate protections for privacy and confidentiality.
 - Whether some form of informed consent should still be obtained.
 - If necessary, subjects and/or the research will be appropriately monitored.
 - Whether any ethical concerns exist
 - Whether the request meets the exemption criteria
4. If the reviewer determines that the activity is exempt from review, the Statement of Exemption Form/discarded specimen/existing medical record/database form is approved. a tracking number will be assigned, and the investigator will be notified and provided with any necessary comments.

5. Once a research study has been certified as exempt, annual reviews are not required; however, investigators are asked on an annual basis to report whether the research is still ongoing and whether all activities still remain exempt.
 - Modifications that fall outside of the exemption categories will require review by the CCI.
 - Exempting an activity from review does not absolve the investigator from ensuring that the welfare of the subjects who participate in the research is protected, and that the methods used and the information provided to gain subject consent are appropriate to the activity. The Director of Clinical Research Compliance or the CCI Chair may still require that a form of consent be obtained, or other safeguards put in place, to protect the human subject.
6. It is the investigator's responsibility to notify the CCI of any changes or modifications that are made to the study's design, procedures, and so on, that do not fall within one of the categories exempted from the regulations.

Related Content

- Statement of Exemption Form
- Clinical Investigation policy [Human Subject Research: Prisoners](#)

Document Attributes

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